NKDEP
National Kidney Disease Education Program

Creatinine Standardization Program

Recommendations for Proficiency Testing and External Quality Assessment Scheme Providers*

The National Kidney Disease Education Program (NKDEP), in collaboration with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Communities Confederation of Clinical Chemistry (EC4), has launched the Creatinine Standardization Program to reduce inter-laboratory variation in creatinine assay calibration and provide more accurate estimates of glomerular filtration rate (GFR). The effort is part of a larger NKDEP initiative to help healthcare providers better identify and treat chronic kidney disease in order to prevent or delay kidney failure and improve patient outcomes.

The Creatinine Standardization Program encourages IVD manufacturers to adjust the calibrations of routine serum creatinine methods to be traceable to the internationally accepted reference method—isotope dilution mass spectrometry (IDMS)—and to work with clinical laboratories to coordinate this calibration adjustment with the introduction of a revised GFR estimating equation appropriate for use with IDMS-traceable creatinine methods.

Proficiency Testing and External Quality Assessment Scheme (PT/EQAS) providers will be crucial partners in the successful implementation of this program, expected to occur during the period between 2006 and 2008. The following steps are necessary to ensure a smooth transition from traditional calibration to IDMS-traceable calibration:

1) Advise participant laboratories that you will be collaborating with IVD manufacturers, IFCC, NKDEP, and EC4 to ensure appropriate grading of PT/EQAS data during a transition period for implementation of the creatinine standardization program.

2) Make necessary changes in participant grading within your respective survey programs during the transition of routine creatinine methods to revised calibrations that are traceable to an IDMS reference method. It is anticipated that bimodal distributions of survey results within a method may be observed. When this occurs, it will most likely be the result of groups of laboratories independently transitioning to new creatinine calibrations for a particular method. This should not be a cause for a given laboratory to fail a PT/EQAS challenge. Thus, it may be necessary for PT/EQAS providers to collaborate with IVD manufacturers to create new instrument/method peer groups (traditional or IDMS-traceable calibration) for their participants that reflect the calibration status of each method that is undergoing a calibration transition for both serum and urine creatinine values.

3) Clearly inform participant laboratories that they will need to choose the correct instrument/method peer group (sub-classified as traditional or IDMS-traceable calibration) for the creatinine calibration in use by their laboratory for a given PT/EQAS challenge.

4) Communicate with IVD manufacturers to obtain their expected dates for introduction of IDMS-traceable calibrations for creatinine for each of their methods, and the anticipated timeframe to achieve completion of the transition for a given method to the new calibration in all routine clinical laboratories using that method around the world.

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* These recommendations update those originally published in *Clinical Chemistry* 2006;52(1):5-18.

Over the longer term, NKDEP recommends introducing a regularly recurring PT/EQAS program that uses commutable serum materials with target values traceable to the IDMS reference method for creatinine. Such a program will allow individual laboratories and IVD manufacturers, on an on-going basis, to assess the performance of routine clinical laboratory methods and the success of the calibration adjustment process for each of their methods. However, IDMS target values should not be assigned to PT/EQAS materials, nor should they be used to evaluate participant performance, unless the materials have been validated to be commutable with native clinical samples for the routine methods being evaluated. For additional information about commutable serum reference materials and their application to PT/EQAS programs, refer to the recent paper: Miller WG, et al. Creatinine measurement: state of the art in accuracy and interlaboratory harmonization. *Archives of Pathology and Laboratory Medicine*, 2005;129:297-304.

More information about the Creatinine Standardization Program and recommendations for other groups, including IVD manufacturers, are available at www.nkdep.nih.gov/labprofessionals.

Contact Information

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